Committee Project Tracking Spreadsheet

Project name	Committees	Federation Project ?	Project Description	Final deliverable (FD)	Date last updated
USP letter related to Maltodextrin	Compendial Review/ Harmonization	N/A	2/16/2021 - USP requested additional information, which is being gathered by member company (Perrigo)	Follow-up comments to USP for proposed Maltodextrin monograph revisions in PF 46 (6)	5/19/2021
IPEC-PDG Working group	Compendial Review/ Harmonization	N/A	IPEC - PDG meeting monograph harmonization	On-going monograph harmonization	5/19/2021
JECFA/Food Related Issues related	Compendial Review/ Harmonization	N/A	Monitor Food Additives issues	on going	5/19/2021
Support Elemental Impurity Coalition	Compendial Review/ Harmonization	N/A	Support Trade Association coalition on the Rationale Implementation of Elemental Impurities	Rationale implementation of Global EI requirements for pharmaceutical excipients	5/19/2021
USP Monograph Modernization Project	Compendial Review/ Harmonization	N/A	IPEC working with USP to modernize monographs. USP currently has unequal API vs NF excipient monographs. The issue is related to level of GMPs,	modernized monographs	5/19/2021
Functional Equivalence of Pharmacopoeias	Compendial Review/ Harmonization	Y	identify and develop IPEC proposals to support pharmacopoeias going forward. This includes general chapter and excipient monograph modernization (e.g. state of-the-industry analytical methods), retrospective recognition of existing excipient monographs and prospective harmonisation of new excipient monographs	1) Industry white paper that identifies the impact of having to comply with multiple compendia on industry and the patient and how companies could use risk assessments and impact assessments to document and justify compendial compliance 2) concept paper and business plan to share with the other associations with proposal to form a broad international consortium to develop a process for collaborating on testing in order to minimize the impact of non-harmonised standards. 3) documented rationale as to why functional equivalence of pharmacopoeias should be considered.	5/19/2021
PQRI Project to compare the BET methods for LAL and rFC.	Compendial Review/ Harmonization	N/A	PQRI Project proposal for study to compare the BET methods for LAL and rFC.	Add rFC to the PDG harmonized method <85> for BET	5/19/2021
Sustainability and Responsible Sourcing	Excipient Qualification	Yes	Develop and publish a Federation guide to add a fourth section to the EIP Guide covering sustainability and responsible sourcing	Published Federation guide covering sustainability and responsible sourcing	5/20/2021
Update Stability Guide	Excipient Qualification	Yes	Develop Federation charter to update current IPEC Stability Guide (2010) and revise guide to include stability gaps not covered in 2010 guide (e.g.	Published revised Federation Stability guide	5/20/2021

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Update of CoA Guide	Excipient Qualification	Yes	Develop Federation charter and update IPEC CoA Guide. This update/revision has been approved by the Federation for a formal project in 2021.	Published revised Federation CoA guide	5/20/2021
Software/hardware to facilitate effective virtual audits	Excipient Qualification	N/A	Develop IA project proposal to prepare list of recommended software/hardware to facilitate effective virtual audits and identify IA members to	Project proposal approved and team identified	5/20/2021
NSF/IPEC/ANSI 363 Standard	Good Manufacturing Practice	N/A	- Ongoing monitoring of ANSI 363 changes and initiatives. - Reporting back to committee on quarterly basis.	ONGOING	5/20/2021
EXCiPACT Standard	Good Manufacturing Practice	Yes	- Ongoing monitoring of EXCiPACT changes and initiatives. - Reporting back to committee on quarterly basis.	ONGOING	5/20/2021
Rx-360	Good Manufacturing Practice	N/A	- Ongoing monitoring of Rx-360 changes and initiatives. - Reporting back to committee on quarterly basis. Mike Polito from Milipore Sigma current IPEC-Americas representative providing feedback to Rx-360 regarding issues that should be clarified or edited which could lead to misunderstandings.	ONGOING	5/20/2021
Rx-360/IPEC Remote Audit Best Practices Guide	Good Manufacturing Practice	Yes	Potential Collaboration Project with Rx-360 on Remote Audit Best Practices Guide	TBD	5/20/2021
IPEC-PQG Excipient GMP How To Guide	Good Manufacturing Practice	Yes	Revised in 2017. Next revision will align with the ISO 9001:2015 and may include development of the how-to guide (see other project listing). IPEC Federation leading revision. Volunteers from different PECs have been added to team. Work to start in 2018	Revise IPEC-PQG Guide	5/20/2021
IPEC GMP Audit Guide	Good Manufacturing Practice	Yes	Update audit guide to align with ANSI 363 Standard. Guide to be used by auditors and manufacturers performing audits to the ANSI Standard	Published IPEC GMP Audit GUIDE	5/20/2021
IPEC-Americas Excipient GMP Audit Gude to ANSI Standard	Good Manufacturing Practice	??	Develop a GMP Audit guide to the NSF/IPEC/ANSI 363 Standard. This guide could then be used as a foundation for the current IPEC GMP Audit guide which has been on-hold since 2018	Published IPEC GMP Audit Guide to NSF/IPEC/ANSI 363 Standard	5/20/2021

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Upper Management Training	Good Manufacturing Practice	N/A	- Need for upper management commitment to GMP - Need for training to engage upper management - Training should capture their attention: - This is how you stay out of jail. - This is how you avoid costly claims	Infographic on upper management responsibilities available	5/20/2021
IPEC Good Distribution Practices Audit Guide	Good Manufacturing Practice	Yes	This guide will draw from applicable sections of the ANSI 363 standard which apply to distributors and is intended be a reference guide for auditors. However, given the status of the IPEC GDP Guide as stated above, this audit guide will be put on hold until completion of the other guide. Prior to initiating work on this audit guide, IPEC- Americas will reach out to IPEC EU for feedback on need and to determine priority.	New GDP Audit Guide	5/20/2021
IPEC Good Distribution Practices How To Guide	Good Manufacturing Practice	Yes	The GDP Guide was revised in 2017. For next revision, this guide would be updated to include information on how to implement the requirements. Need to prioritize this project based on resources. On hold for now. GDP Guide members: Lisa Frame, Erica V., Luc S. with Charlotte M. - lead	Published GDP How To Guide	5/20/2021
GDP FAQ	Good Manufacturing Practice	Yes	Develop / post FAQ based on Q&A received during the IPEC-Americas "Good Distribution practices and buyig through distribution" Webinar held 8/26/2020.	Published GDP FAQ	5/20/2021
Develop PQRI Continuous Manufacturing Workshop	Quality by Design	N/A	PQRI sponsored workshop for API and excipient impact on continuous manufacturing.	PQRI CM Workshop scheduled and executed	5/20/2021
Develop PQRI Workshop proposal for ICH M9 EWG Oral Bioavailability Project – Phase II	Quality by Design	N/A	ICH M9 EWG next meets in autumn. Dave Schoneker proposed IPEC work with PQRI on a workshop to gather information needed to support ICH M9 project	PQRI ICH M9 workshop on excipient/API Interactions	1/5/2021
ICH Continuous Manufacturing (Q13)	Quality by Design	Yes	Brian C. to represent IPEC on ICH Q13 Working Group. He will provide updates/drafts from WG activities, as allowed.	ICH Q13 CM Guideline	5/20/2021

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Update definition for excipient impurities/ concomitant components	Quality by Design	Yes	Formation of a new project team, pulling together members from different committees (e.g., QbD, GMP, etc.), to better understand and define excipient impurities and concomitant components as well as develop a strategy moving forward, including potential revisions to the recently published IPEC Glossary and Composition Guide.	Updated definition for excipient impurities and concomitant components. Defined strategy to communicate (e.g., infogrphic), and where necessary, update IPEC documents.	5/20/2021
Excipient Communication Tool	Quality by Design	N/A	Project to develop an "excipient communication tool" that would provide a mechanism/process by which excipient manufacturers would/could share information with excipient users on the variability of the excipients they supply	Excipient variability information sharing tool	5/20/2021
FDA meeting on additives and processing aids in pharmaceutical excipients	Quality by Design	N/A	Revive backgrounder previously developed for FDA and circle back to FDA regarding request for a meeting to discuss the importance for how to handle information pertaining to additives and process aids in drug applications	Infographic on importance of additives and process aids for FDA	5/20/2021
New, more sensative analytical technology applied to excipients	Quality by Design	N/A	To address how new, more sensitive analytical methods could impact concerns related to excipient composition, collect feedback from members on issues related to characterizing excipients using new analytical techniques (e.g., identification or new peaks due to more sensitive techniques may lead to a misconception that the excipient contains new compositional impurities). Develop position paper, including unintended consequences.	Positon paper on issues related to new analytical techniques	5/20/2021
FDA IPEC excipient GMP training	Quality by Design	N/A	Rick Friedman (FDA) organizing IPEC-Americas training for FDA personnel regarding QMS expectations at excipient firms focusing on ANSI 363 excipient GMPs.	FDA training on QMS expectations at excipient firms completed	5/20/2021
Compound Pharmacy Association – outreach	Regulatory Affairs	N/A	Reach out to compounding pharmacy trade associations for joint collaboration/membership.	Collaboration/membership with compound pharmacy organizations/personnel	9/30/2020

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Highlight excipient information on US Laws, regulations and industry best practices	Regulatory Affairs	N/A	IPEC-Americas is currently developing some short briefs, infomercials and fact sheets highlighting basic regulations on excipients (where applicable, include information on plastics ban), filings/registration requirements, labels, re-evaluation testing, shipping labels/shipping requirements (bags, pallets, containers), GMP/quality standards, need for translation into local language, recent regulations, stability, independent certification, foreign registration certification, etc.	Short briefs, infomercials, fact sheets and documentation to communicate the value IPEC-Americas brings	5/19/2021
Explore membership expansion into combination products	Regulatory Affairs	N/A	Explore expanding IPEC membership to companies producing combination products. Priscilla to contact someone at Dow. Irwin S. agreed to support team.	Feasibility for expanded IPEC membership	12/9/2020
FDA IID update	Regulatory Affairs	N/A	Support FDA clean-up and update of US FDA IID	Improved FDA IID database and process for toxicology assessments for families of similar products	5/19/2021
Emerging regulatory Hot Topic - hand sanitizer	Regulatory Affairs	N/A	Monitor emerging "hot topics" globally, share, as appropriate and determine whether further action is warranted	Communication (updates) and potential actions	9/30/2020
CROSSFUNTIONAL TEAM - nitrosamines	Regulatory Affairs	N/A	Monitor emerging "hot topics" globally, share, as appropriate and determine whether further action is warranted	Communication (updates) and potential actions	5/19/2021
CROSSFUNTIONAL TEAM - microplastics	Regulatory Affairs	N/A	Monitor emerging "hot topics" globally, share, as appropriate and determine whether further action is warranted	Communication (updates) and potential actions	5/19/2021
Atypical Actives Position Paper (Revised) and FAQ	Regulatory Affairs	TBD	* Revised position paper (TBD if necessary) * Develop a FAQ to address atypical actives with regard to regulatory expectations * This may also lead to development of other documents e.g. FAQs on CEPs, DMFs etc relative to excipients * Seek opportunities to engage with regulators/industry on this topic	1) Position paper or FAQ on how regulatory issues with atypical actives might be handled 2) FAQs or other documents on related topics (relevance of CEPs, DMFs, etc) 3) External presentations to share information on atypical actives	5/19/2021
Global regulatory requirements for excipients	Regulatory Affairs	Yes	Project to find the regulatory requirements for Excipient in different countries (Decernis database collaboration)	A definitive report on the stability study methods and expiry date on excipients	5/19/2021
IQ Initiative	Scientific Affairs	N/A	IPEC-Americas and IQ Consortium to collaborate with FDA to propose/develop new "novel excipient qualifying process."	FDA supported "novel excipient qualification process"	5/18/2021

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TiO2, nanoparticles	Scientific Affairs	TBD	Follow evolving TiO2 activates in France targeted at banning TiO2 from foods	Understanding of impact of TiO2 activities on pharmaceutical products/ingredients	5/18/2021
Update IPEC-Americas Safety Guide	Scientific Affairs	TBD	Revise previous IPEC-Americas Guide, published in Regulatory Toxicology and Pharmacology, Volume 24, No. 2, October 1996.	An updated guide for the types of safety testing needed for a product approval	5/18/2021
SOT Annual Meeting Poster to promote new Safety Guide	Scientific Affairs	Yes	Develop poster for SOT Annual Meeting (March 2, 2021).	SOT Poster presented at 2021 SOT Annual Meeting	5/18/2021
PQRI Project on polymeric chain length on absorption	Scientific Affairs	N/A	Support PQRI project to address polymer absorption based on molecular chain length.	Publication on how to address absorption based on molecular chain length	2/23/2021
CRS Annual Meeting presentation to promote new Safety Guide	Scientific Affairs	N/A	Develop presentation for on IPEC Safety Guide for CRS Annual Meeting (July 25-29, 2021).	IPEC Safety Guide presentation at 2021 CRS Annual Meeting	5/18/2021
CPhI Annual Meeting educational pod cast	Scientific Affairs	N/A	CPHI Collaboration – Educational Programming/Pod Cast - Drug Safety and Quality. Potential topic TiO2	IPEC-Americas CPhI TiO2 podcast	5/18/2021